

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER      020707**

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**CORRESPONDENCE**

NDA 20-707

MAR 15 1996

Sanofi Winthrop, Inc.  
Attention: George Clay, Ph.D.  
Great Valley Parkway  
P.O. Box 3026  
Malvern, PA 19355

Dear Dr. Clay:

We have received your new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Skelid (tiludronate disodium) 200 mg Tablets

Therapeutic Classification: Standard

Date of Application: February 28, 1996

Date of Receipt: February 28, 1996

Our Reference Number: 20-707

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on April 28, 1996, in accordance with 21 CFR 314.101(a).

Under 21 CFR 314.102(c) of the new drug regulations and in accordance with the policy described in the Center for Drug Evaluation and Research Staff Manual Guide CDER 4820.6, you may request an informal conference with this Division (to be held approximately 90 days from the above receipt date) for a brief report on the status of the review but not on the application's ultimate approvability. Please request the meeting at least 15 days in advance. Alternatively, you may choose to receive such a report by telephone. Should you wish a conference, a telephone report, or if you have any questions concerning this NDA, please contact:

Randy Hedin, R.Ph.  
Consumer Safety Officer  
Telephone: (301) 443-3520

Please cite the NDA number listed above at the top of the first page of any communications

concerning this application.

Sincerely yours,

CCP

3/15/94

FOR

Enid Galliers  
Chief, Project Management Staff  
Division of Metabolism and  
Endocrine Drug Products (HFD-510)  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

cc:

Original NDA 20-707  
HFD-510/Div. Files  
HFD-80  
HFD-510/CSO/R.Hedin  
Concurrence: EGalliers 03-01-96\ft/nm 03-13-96

drafted: RH/March 1, 1996/N20707AC.LT1

Final:

ACKNOWLEDGEMENT (AC)